# Exempt Determination

**ALVERNO COLLEGE INSTITUTIONAL REVIEW BOARD**

This form is used to apply to the Alverno IRB for an Exempt Determination. A study is declared "Exempt" if it presents no more than minimal risk to participants and the participants (or their parents/guardians, in the case of children) are able to make a free and informed decision about whether or not to participate. Federal regulations limit exemptions to studies fitting into one or more of a set of exemption categories. In addition, research receiving federal funding (e.g., as part of a grant) does not qualify for Exempt status.

Alverno policy requires that the Exempt determination must be made by someone other than the investigator(s). A trained reviewer will examine your application for Exempt Determination as well as your Research Protocol to determine whether or not your study qualifies as Exempt. The reviewer will verify that the study:

- does not exceed minimal risk,
- that the participants do not belong to a "vulnerable population" (which would put them at more than minimal risk and/or prevent them from making a free and informed decision about participation, and
- that the study does not receive federal funding.

A study that does not qualify for Exempt status may still be conducted if it receives IRB approval through the standard (non-Exempt) procedures. If your request for Exemption is denied you may pursue approval through that route.

Each section of this document contains descriptive information followed by directions on how to provide the information the reviewer will need in order to make the Exempt determination. Be sure to address all of the items in the Directions sections.

This Exempt Determination document must be accompanied by a completed Research Protocol form.

## Study Identification

Principal Investigator: _____

Study Title: _____

IRB# (assigned by IRB): _____

Date: _____

# Automatic Disqualifiers

Certain categories of participant automatically disqualify research from Exempt determination. Note that these are automatic disqualifiers that you can use to quickly determine whether you should continue to apply for an Exempt determination. Note that if your study includes none of these automatic disqualifiers it may still not qualify as Exempt research.

If your study collects data from participants in any of these categories the study is not Exempt because free informed consent cannot be guaranteed:

- Prisoners
- Participants who are unable to understand what consent implies and have no legal surrogate consent
- Children who are connected to the research setting as patients
- Pregnant women who are connected to the research setting as patients

There are also measurements and research activities that disqualify research from Exempt determination because they elevate the risk to participants beyond "minimal risk":

- Use of sexually explicit materials or gathering data about explicit sexual behavior or experience
- Sensitive information such as about sexual experience, illegal substance use/abuse, mental illness
- Use of an FDA regulated product such as a drug or medical device, or the use of radiation
- Elevated or non-routine physical activity
- Collection of blood, secretions, or other bodily material
- Invasive medical procedures
- Collection of protected health records with direct or indirect identifiers
- Association with illegal or illicit activities.

### Directions:

Write a statement that certifies that your research proposal does not include any of the disqualifying participants or measurement and research activities.

If your study **does** include any of these disqualifiers then it does not qualify for Exemption. You may submit a proposal under the standard procedure and explain in that submission how you intend to protect the participants despite the elevated risk and/or inability to get full consent.

# Analysis of Risks and Benefits

In this section you will describe the risks to participants presented by your study, and the measures you will take to minimize those risks. The standard for Exemption is that a study present participants with no more than "minimal risk", which is defined in 45 CFR 46.102:

**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Risk" implies potential. For example, if you are collecting employees' opinions about their employer you should recognize the risk that some of those opinions may be unpopular with the employer. Were the employer to become aware that a particular employee holds such an opinion the employer might retaliate against the employee. In your analysis of risks you would identify this possibility and talk about what you intend to do to prevent it from occurring.

You will also identify any benefits to the participants. The analysis of risks and benefits involves weighing the risks and benefits to the participants to determine if the risks are justified. However benefits are **not** to be used to entice participants into participation. If you used the promise of a gift certificate to entice employees to give their opinions about their employers you would have undermined the employees' right to make a free informed judgment about their participation in your study.

### Directions:

Identify any risks to participants presented by participation in your study as well as any efforts to avoid or minimize those risks. Also identify any direct benefits to participants and explain why those benefits will not entice participants to participate despite the risks. Make a case that participation in your research involves no more than minimal risk.

## Informed Consent and Vulnerability

In this section you will describe your plans to gather and document informed consent from your participants. The principles of ethical treatment of research participants requires that the researcher obtain freely given informed consent for participation from each participant. "Freely given" means that the participants are not coerced, bribed, or threatened into participation. "Informed" means that they are provided with information about the research and about their participation in the research as well as the opportunity to ask additional questions that they might have about their participation. The information must be provided in a format that is understandable to each participant, so in an appropriate language and at an appropriate reading level. It is the researcher's responsibility to ensure that the participants understand what they are asked to consent to.

Some potential research participants cannot legally give consent for their own participation. In most cases the free informed consent of a parent or legal guardian of such a participant can substitute for the participant's own consent. In such cases the positive assent of the participant should be sought. In practical terms that means that even if you have consent from the parent or guardian of a child or of an adult who cannot legally give consent, you should make a reasonable effort to respect that child or adult's own wishes about whether or not to participate. Parental consent does not mean that a child must participate if that child does not want to.

For the purposes of IRB evaluation, the term "children" is defined by 45 CFR 46.402:

**Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Generally this means that a person is a child until reaching the age of 18 years. However college students below the age of 18 are considered adults who can give consent for participation.

Participant consent is typically documented through signed and dated consent forms which the researcher retains for a reasonable time after the study is completed. It is the researcher's responsibility to gather and retain that documentation of consent.

In some cases Exempt research can be conducted without documentation of consent. When a study collects anonymous data the risk to participants can be elevated by documenting each participant's consent. It may be preferable to inform the participants about the nature of the study and of the risks of participation and then inform them that if they choose to provide information it will be assumed that they have consented to participate. In that situation the researcher will not collect any participant signatures to consent. The most common example would be an anonymous survey collecting sensitive information. In such a case documentation of consent would be the only link between responses and the identity of the participants, and signed consent forms would elevate the risk to those participants.

Research participants have specific rights as participants, and informed consent documents must inform those participants of their rights.

- The right to refuse to participate.
- The right to withdraw from participation during the study. As long as it remains possible to remove a participant's responses from the data collected the participant has the right to have those responses removed. Obviously at some point in the analysis and reporting this is no longer possible, but the participant can withdraw up to that point.
- The right to ask questions about participation. When a study requires that some information be withheld from the participants the participants have the right to a debriefing after the study is completed.
- The right to direct complaints, questions, or issues concerning their participation to someone in authority other than the researchers themselves. Typically this means providing participants with contact information for the IRB Chair (irbchair@alverno.edu).

## Directions:

Describe how you intend to collect informed consent from your participants. Include copies of your consent letters or of the materials you will present to potential participants to inform them about your study and their participation. If you intend to waive documentation of consent indicate that and explain why documentation of consent elevates the risk to the participants.

It is assumed that your materials including consent materials will be in English. If you anticipate that some of your participants are not native English speakers describe how you will ensure that all of your participants can understand your consent materials and meaningfully evaluate the risks and benefits of participation.

If your participants include children indicate how you will obtain and document free informed consent from their parents and/or legal guardians. For documentation purposes be mindful of the fact that the child's last name and the parent's or guardian's last name may not be the same. Explain how you will ensure that you can identify the appropriate consent form for each child if you are required to produce that form.

# Categories of Exemption

All research activities in an Exempt research project must fall within one or more of the federally defined Exempt categories. In this section you will identify the Exempt category or categories that your research fits. Any research that includes research activities that do not fit into these categories is not Exempt.

Note that the first three categories will be the most common. We will describe those in detail, and give only brief descriptions of Categories 4-8. (Decriptions are from 45 CFR 46.104)

**Category 1** – Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

This category is defined by the setting and the nature of the activity. A study can be Exempt Category 1 if

- It is conducted in an educational setting (typically a school) and
- It involves normal educational practices.

This category includes research into the effectiveness of educational methods, curricula, classroom management methods, and assessment methods.

**Category 2** - Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

This category includes research involving tests, surveys, interviews, and/or observations of behavior. To qualify as Category 2 one of three additional criteria must be met:

- The information recorded must be stored in such a way that a person who has access to that information cannot identify the participants.
- The information must not be sensitive, in the sense that if the participants' responses were to become known that would not be damaging to the participants in any significant way, or
- The IRB has conducted a "limited IRB review" and is reassured that the participants' privacy is protected and the data remain confidential.

Anonymous surveys meet the first of these three requirements.
Surveys or interviews about non-sensitive topics will generally meet the second requirement (the participant should be well-informed in advance of consent about the nature of the questions).

Confidential surveys or interviews or other research about sensitive topics may meet the third requirement if the IRB determines that the researchers' plans for maintaining the participants' privacy are sufficient protection.

**Category 3** - Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 3 involves research in which some behavioral intervention is used and data are collected verbally, in writing, or through audiovisual recording. To meet Category 3 the research must gather consent in advance from the participants to participate in the intervention and to have the data collected. Category 3 research must also fit one of the three additional criteria (see Category 2) about anonymity, privacy, and data sensitivity.

*Category 3 and Category 2 Exempt research differ in that Category 3 research involves a behavioral intervention, and the researcher must obtain prior consent from the participants to participate in that intervention and the data collection. Category 2 research does not involve interventions.*

**Category 4** - Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens

**Category 5** - Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research

**Category 6** - Taste and food quality evaluation and consumer acceptance studies

**Category 7** - Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research

**Category 8** - Research involving the use of identifiable private information or identifiable biospecimens for secondary research use

## Directions:

Identify the category or categories into which your research activities fall and explain your reasoning.

If you are conducting educational research in an educational setting, your research may be Category 1.

If you are conducting tests, surveys, interviews and/or observations of public behavior outside of educational settings and not involving any interventions, your research may be Category 2. If you identify your research as Category 2, explain which of the three additional criteria your privacy efforts meet.

If you are using a behavioral intervention and conducting tests, surveys, interviews and/or observations of public behavior outside of educational settings, your research may be Category 3. If you identify your research as Category 3, explain which of the three additional criteria your privacy efforts meet.